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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,510	12/05/2003	Kazuhisa Fukushima	032094	7859

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WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP
1250 CONNECTICUT AVENUE, NW
SUITE 700
WASHINGTON, DC 20036

EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/727,510

Applicant(s)

FUKUSHIMA ET AL.

Examiner

Jeanine A. Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Finality of the action mailed October 31, 2006 has been withdrawn.
2. This action is in response to the papers filed February 27, 2007. Currently, claims 2-5, 7 are pending.
3. All arguments have been thoroughly reviewed. This action is made FINAL.
 - a. The terminal disclaimer filed August 18, 2006 has been reviewed and approved.
 - b. The arguments directed to Chee filed 2/27/07 have been thoroughly considered and deemed persuasive.
4. Any objections and rejections not reiterated below are hereby withdrawn.
5. This action contains new grounds of rejection necessitated by amendment to the claims filed August 18, 2006.

Election/Restrictions

6. Applicant's election without traverse of Group 1, Claims 1-5 in the paper filed January 3, 2006 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Priority

7. This application claims priority to Japanese Appln No. 2002-353559, filed December 5, 2002.

It is noted that a translation of the foreign document has not been received.

Drawings

8. The drawings are acceptable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2, 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanian et al. (WO 00/06770, February 10, 2000) in view of Bruchez et al. (US Publication 2001/0034034 A1, October 2001).

Balasubramanian teaches arrayed biomolecules and their use in sequencing. Balasubramanian teaches a method of using an array which has a surface density which allow molecules to be individually resolved by optical microscopy. The method uses arrays which may be formed by simply immobilizing a mixture of molecules to a solid surface in such a way that provides sufficient separation between the molecules to allow each molecule to be resolved optically. The molecule is immobilized at one or more points by specific interaction with the surface (page 2, lines 29-32).

Balasubramanian teaches that the arrayed molecules may be immobilized on a solid support via micorspheres (page 3, lines 15-17). Balasubramanian teaches that the micorspheres are functionalized polystyrene latex microsphere (page 15)(limitations of Claim 4). Balasubramanian teaches that many thousands of reactions can be detected at the same time with no phasing problems (page 3, lines 32). The array of polynucleotides are contacted with a plurality of detectably-labeled fragments of an organism's genomic DNA under hybridizing conditions and detecting hybridization (page 4, lines 13-16). As seen in Figure 2, the immobilization of a polynucleotide to a solid surface via a microsphere is illustrated. Balasubramanian teaches that the arrays may comprise protein molecules immobilized on a solid surface, the protein molecules being conjugated with or otherwise bound to a short polynucleotide molecule may be

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interrogated, to address the array (page 6, lines 14-16). Balasubramanian teaches that the surface of the solid support may be coated with streptavidin or avidin and then a dilute solution of a biotinylated molecule is added at discrete sites on the surface (page 8, lines 1-4). If the molecule is a polynucleotide then immobilization may be via hybridization to a complementary nucleic acid molecule previously attached to a solid support (page 8). Balasubramanian teaches that short sequences that a protein binds to may be used to find all the transcription-controlling proteins or cDNA (page 13)(limitations of Claim 5). Much like the schematic filed in the after-final amendment of 2/27/07, Figure 2 illustrates a protein interaction on the solid surface which immobilizes a bead with nucleic acid molecules which have been hybridized with sample and labels. Balasubramanian teaches that "spatially addressable" is used to describe how different molecules may be identified on the basis of their position on an array (page 10, lines 15-20).

Balasubramanian does not specifically teach spatially addressing the beads by an antigen-antibody reaction.

However, Bruchez teaches a method of detecting an analyte in a sample using antibody-antigen interactions. Bruchez teaches immunoassays such as enzyme-linked immunosorbent assays are used in numerous diagnostic, research and screening assays. ELISA detects the presence and/or concentration of an analyte in a sample using an antibody which specifically recognizes the analyte. The analyte is either immobilized directly onto a solid support or is bound to a different specific antibody which itself is immobilized on a solid support (para 3). As seen in Figure 1A and 1B, an

antigen is immobilized and an antibody is bound and detected. Bruchez specifically illustrates antigens immobilized on microspheres which could be made of various chemistries (Figure 1C). Bruchez teaches exemplary binding pairs include any haptenic or antigenic compound including digoxigenin and anti-digoxigenin, for example. Bruchez specifically describes a sandwich assay of Figure 1 which uses an antibody, antigen complex and a third detection antibody (Example 1).

Therefore, it would have been prima facie obvious at the time the invention was made to have modified the protein interaction of Balasubramanian with the specific antibody/antigen interaction taught by Bruchez. Bruchez teaches that the antibody/antigen interaction allows for very specific identification of analytes. The antibody/antigen interaction is a simple detection means. Bruchez further teaches exemplary binding pairs are antibody/antigen pairs. The ordinary artisan would have been motivated to have modified the protein interactions of Balasubramanian with the more simple and highly specific binding pairs of Bruchez, namely antigen/antibody pairs.

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanian et al. (WO 00/06770, February 10, 2000) in view of Bruchez et al. (US Publication 2001/0034034 A1, October 2001) as applied to Claims 2, 4, 5, 7 above and further in view of Collier et al. (US Pat. 5,985,548, November 1999).

Neither Balasubramanian nor Bruchez specifically teach a method of stirring beads.

However, Collier teaches beads and test mixtures are agitated to assure contact with the bead supports (see Example 2).

Therefore, it would have been prima facie obvious to the ordinary artisan at the time the invention was made to have added an agitation or stirring step to the bead method of Balasubramanian in view of Bruchez for the expected benefits taught by Collier. Collier specifically teaches the ordinary artisan would be motivated to agitate bead and test mixtures to assure contact with the bead supports. Thus, in order to ensure contact of the beads and mixtures, the ordinary artisan would have included an agitation step.

Conclusion

12. No claims allowable over the art.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.



Jeanine Goldberg

Primary Examiner

April 2, 2007